

*The Farrak Fawcett Foundation.*



June 22, 2011

Advisory Committee on Immunization Practices  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E., Mailstop E-05  
Atlanta, GA 30333

Dear Members of the Committee:

We write to you as a coalition of health care organizations committed to reducing rates of anal cancer and the virus that causes the majority of the cases, human papillomavirus (HPV). We urge you to recommend routine vaccination against HPV for males. We have also attached the more detailed letter we submitted as testimony to the February meeting of the Advisory Committee on Immunization Practices (ACIP) on this topic.

We commend the steps the ACIP has already taken to reduce HPV-associated cancers by issuing a routine recommendation for women to immunize against HPV. We encourage you to take the next step for men by elevating the male vaccine from permissive to routine status. Our reasons include:

- **HPV causes cancer and precancer in both males and females.** Each year, over 28,000 people in the United States are diagnosed with a cancer caused by HPV. This includes anal, cervical, vulvar, and vaginal cancers in women, anal and penile cancer in men, and head and neck cancers in both genders. HPV also causes genital warts.
- **The federal government has recognized the benefits of the vaccine.** The Federal Drug Administration has stated that the quadrivalent HPV vaccine protects against the development of anal, cervical, vulvar and vaginal cancers, as well as genital warts. The ACIP has issued routine recommendations for women and permissive recommendations for men to obtain the vaccine for the prevention of these cancers.
- **The vaccine is our best chance at preventing HPV-associated malignancies.** Even with the benefits of cervical cancer screening, over 12,000 women are diagnosed with cervical cancer each year. For head and neck cancers, it has been a

challenge to implement successful screening protocols to detect early stage disease. The lack of screening protocols for all HPV-associated cancer sites and the fact that systemic therapies for those with advanced HPV-associated disease are limited means that we can greatly reduce the risk of entire generations developing cancer by vaccinating both males and females.

- **The vaccine protects against the HPV types that cause the majority of HPV-associated anal cancer.** 80-90% of anal cancer is caused by HPV and most of that population has cancer caused by HPV-16 or HPV-18. Protecting against these types will dramatically decrease the amount of people living with anal cancer.
- **Vaccination rates for females are very low, and rates for males are even lower.** By routinely vaccinating men we can actively protect larger numbers of the population. The governments of the United Kingdom and Australia have much higher female vaccination rates than the United States, which means they will see a lower cancer burden in the coming decades.
- **The community of men-who-have-sex-with-men (MSM) is especially at risk, and they are not protected by herd immunity that may exist from female vaccination.** The MSM population deserves the same protection against cancer as the partners of vaccinated women. With the challenges that exist with access to care, making vaccination for males routine will cause more doctors to speak with boys about immunization. Additionally, many young men may not identify as MSM before they become sexually active when the vaccine is most effective. Immunization before sexual activity will help prevent cancer in men irrespective of their partner's gender.
- **Anal cancer and precancer is difficult to have and to treat.** The therapeutic treatments that accompany an anal cancer diagnosis are often toxic and uncomfortable. The stigma associated with anal cancer can present social challenges for patients living with the disease. With a vaccine that can protect against anal cancer, we urge the government to use this available tool to prevent its citizens from developing the disease and the physical and social obstacles that accompany it.
- **Anal cancer is increasing.** Anal cancer rates are increasing across all genders. This is especially true in the HIV-positive community, where antiretrovirals have resulted in a longer life, but the complications of a suppressed immune system mean that it is easier for the virus, HPV, to cause the abnormalities that lead to anal cancer.

We urge you, as members of the body charged to evaluate immunization programs, to consider the impact you will have on future generations of Americans. A vaccine exists that can decrease stigmatized and painful diseases from development in thousands of people. Please use your capacity as advisors to the federal government to advance a routine recommendation for males.

We encourage you to revisit our February letter, which addresses the preceding points in detail. Thank you for your consideration of this testimony.

Sincerely,



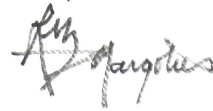
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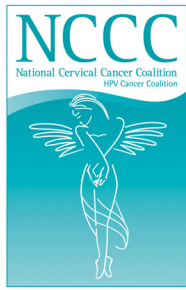
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February 23, 2011

Advisory Committee on Immunization Practices  
Centers for Disease Control and Prevention  
1600 Clifton Road, N.E., Mailstop E-05  
Atlanta, GA 30333

Dear Members of the Committee:

We write as a coalition of organizations deeply concerned about anal cancer and the virus that causes the majority of cases, human papillomavirus (HPV). Please accept this letter in lieu of testimony for the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) hearing on February 24th to consider routine vaccinations to prevent HPV and the cancers they cause in men and women.

We are encouraged that the Food and Drug Administration's (FDA) approval of the anal cancer indication for the quadrivalent HPV vaccine means women will now be routinely recommended to vaccinate against anal precancer and cancer, in addition to cervical, vulvar and vaginal cancers. While we understand that no vote will be taken at the hearing, we urge you to build on the FDA's approval of the anal cancer indication and to extend routine recommendations for the HPV vaccine to include men. By preventing the most carcinogenic HPV infections, the HPV vaccine has great potential to prevent the chronic conditions, painful cancer treatments and deaths that result from the virus.

HPV, which causes cervical, anal, vulvar, vaginal, penile and head and neck cancers, is the most common sexually transmitted virus in the United States. It also causes genital warts, which can have negative social and sexual implications. According to the American Social Health Association, 75% of the United States population between the ages of 15 and 49 has had an HPV infection in their lifetime. Although the majority of HPV infections are fought by the immune system and do not become cancer, there are around 15 oncogenic HPV types that can lead to diminished quality of life and death.

HPV-related precancer and cancer morbidity is a significant burden – physically, emotionally, and financially – on patients and the healthcare community. While cervical cancer rates have fallen in recent years thanks to routine diagnostic tests such as the Pap smear, over 12,000 women are diagnosed with cervical cancer annually in the United

States, indicating that many women are still slipping through screening protocols. In the meantime, HPV-related cancers in other sites, such as the mouth and anus, are on the rise.

Anal cancer is a serious disease diagnosed in over 5,200 people a year and the incidence is growing. The leading cause of anal cancer – at 80 - 90% – is HPV. Unfortunately, anal cancer screening is not widespread. There is still much debate on the best screening practices within the clinical community. Many at-risk people do not know that they should be checked for anal cancer. Cancer therapies have not improved significantly in decades and late stage HPV-related cancer patient outcomes are still very poor. While we are hopeful the low number of therapeutic options may change in the future, our greatest prospect for putting a stop to death and illness related to HPV-associated cancer is prevention, education, and screening.

The quadrivalent vaccine, which protects against the HPV types that most commonly cause HPV-associated cancers, remains our best tool to reduce mortality and morbidity related to these diseases. It is unlikely that new therapeutics will be commercialized and nationwide screening programs will be implemented in the near future in a manner that will lead to a significant shift in early diagnosis and treatment of these diseases. United States inoculation rates for the vaccine are significantly less than other developed countries such as the United Kingdom and Australia. At such low rates, the United States population does not benefit nearly as much as it could from herd immunity through the vaccination of women. The routine vaccination of men provides an excellent opportunity to safeguard the entire population against diseases that otherwise lack sufficient resources.

### **The Federal Government Has Recognized the Benefit to Vaccinating Against HPV**

We commend the steps the FDA and ACIP have already taken to reduce HPV rates in the United States. From 2006 to 2009 the ACIP made a series of recommendations that included routine vaccination for the prevention of the HPV types that most commonly cause cervical, vulvar and vaginal cancers and genital warts in women. In men, the ACIP also provided guidance that the vaccine may be given to reduce the likelihood of acquiring genital warts. Specifically, the FDA approved the quadrivalent vaccine, Gardasil, to protect from HPV-16, HPV-18, HPV-6 and HPV-11, and the bivalent vaccine, Cervarix, to protect against HPV-16 and HPV-18.

The FDA announced in December 2010 that the quadrivalent vaccine also protects against anal precancer and cancer. Dr. Karen Midthun, Director of the FDA's Center for Biologics Evaluation and Research, stated in December that the vaccine "as a method of prevention is important as it may result in fewer diagnoses and the subsequent surgery, radiation or chemotherapy that individuals need to endure." The data submitted to the FDA illustrated that preventing infection by HPV-16 and HPV-18 would lead to significantly reduced rates of anal precancer and cancer, as many cell abnormalities are caused by these HPV types.

## **HPV Leads to Precancer and Cancer in Both Men and Women and Should be Actively Prevented in Both Populations**

By making the HPV vaccine more accessible to the public, the United States will provide for its citizens the ability to drastically reduce their exposure to the most common HPV types that progress to anal precancer and cancer, in addition to other HPV-related cancers, in men and women.

The need for the vaccine is particularly high for men-who-have-sex-with-men (MSM). While the absolute number of people annually diagnosed with anal cancer is larger for women, the MSM population has the highest incidence of the disease. HIV-negative MSM are seventeen times more likely to develop anal cancer and HIV-positive MSM are twice as likely as HIV-negative MSM to develop it. The HPV vaccine should be recommended for routine vaccination in all boys as MSMs may not self-identify until sexual activity has already commenced. Additionally, HPV is also present among the heterosexual male population leading to anal cancer, genital warts and HPV transmission.

We look forward to the decreased rates of anal precancer and cancer with the FDA recognition that the quadrivalent vaccine protects against anal cancer and the forthcoming inclusion of the anal cancer indication in routine recommendations for women. Of the estimated 3,260 women diagnosed with anal cancer last year, a significant number were caused by HPV-16 and HPV-18. By extending routine vaccinations to include anal cancer, you will be increasing comprehensive protection against a multitude of HPV-related conditions in women. Furthermore, if all boys are similarly vaccinated, the number of women who encounter HPV-related cancers through sexual activity will decrease.

### **Anal Precancer and Cancer Is Difficult to Have and to Treat**

Patients living with anal cancer face a physical battle with a painful disease and grueling treatment and surgeries. The body endures chemotherapy drugs, causing prolonged fatigue, extreme nausea, and debilitating chronic pain. Radiation to a very sensitive part of the body can cause diarrhea, changed sexual functioning, extreme burns, bleeding and long-term gastrointestinal complications. Some patients require body-changing ostomies.

Unfortunately, treatment for the disease has not changed in decades and therapeutic measures to treat patients are not improving. There has been minimal funding for studies to make treatment less toxic and uncomfortable. With a vaccine available to protect against this physically-draining disease, the ACIP has the ability to improve the lives of thousands of people, and to save lives that might be cut short from anal cancer.

We must also highlight the terribly oppressive social stigma associated with anal cancer. Anal cancer is a difficult disease for patients to openly discuss with their doctors, colleagues and loved ones, a challenge that makes dealing with this cancer even more difficult than its physical burden alone. This stigma prevents equitable conversation, education and resources for the patients who have this disease.

HPV also causes the precancerous lesions that lead to anal cancer called Anal Intraepithelial Neoplasia (AIN). While not generally life-threatening, AIN can drastically affect a person's quality of life long before it becomes invasive cancer. The treatment for persistent anal precancer is frequently uncomfortable and can have lifelong side effects. These patients need to be closely monitored and often have to return for multiple treatments. By encouraging wide-spread vaccination for young men and women, the ACIP will actively decrease the impacts of this painful, and often chronic, condition. Furthermore, wide-spread use of the vaccine will also provide protection against warts, which do not generally cause cancer, but are an often uncomfortable and embarrassing symptom.

### **The Vaccine Provides the Best Mechanism to Prevent Anal and HPV-Associated Cancers**

Increasing vaccination rates is an essential step in preventing all HPV-caused cancers. Unfortunately, vaccine coverage is currently very poor in the United States. In 2009, just 44% of adolescent girls received one dose of the vaccine and approximately 25% received all three doses. With more wide-spread vaccination rates, we would see a reduction in the numbers of people – both men and women – living with HPV-associated and anal cancers. In other countries like the United Kingdom and Australia, vaccination rates are much higher. In the United States, we need to vaccinate both men and women in order to protect the largest numbers of the population possible against the HPV-related precancers and cancers that affect the anus, cervix, vulva, vagina, penis, head and neck.

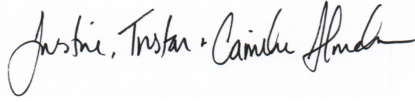
While we limit our communication today to our support for a routine vaccination program, we note that improved and increased screening protocols to detect precancerous lesions would go a long way to reducing the number of cancer diagnoses and deaths. In addition, the quadrivalent vaccine only protects against HPV types 6, 11, 16 and 18, which will mean screening will continue to be necessary to find cancers caused by other HPV strains.

We also appreciate that there is a cost-effective argument under consideration by the ACIP. We urge the federal government and Merck, GlaxoSmithKline, as well as any other pharmaceutical company in the HPV field, to work together to bring the cost of the vaccine down.

The recommendation to vaccinate men and women routinely against anal precancer and cancer presents an effective mechanism to stop the social stigma, chronic conditions, cancers and deaths that can result from exposure to HPV. A large-scale vaccination program will decrease HPV infection and transmission and directly lead to a reduction in HPV-associated cancers and genital warts. The benefits of vaccinating adolescent women and men won't reduce the incidence of anal cancer for years. That, in addition to the low United States vaccination rate, means that we must take immediate steps to reducing HPV-associated precancers and cancers. We urge you to extend the routine recommendation to men and decrease the burden of HPV and its resulting conditions. Increased access to HPV vaccination will translate directly into saved lives.

Thank you for your consideration of this testimony.

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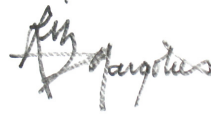
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